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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/892,993 | 06/27/2001 | Kelly R. Brown | ETH-1567 | 3764 |

7590

08/12/2003

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EXAMINER

FUBARA, BLESSING M

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 08/12/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/892,993

Applicant(s)

BROWN ET AL.

Examiner

Blessing M. Fubara

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 25-28 is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☒ Claim(s) 24 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Examiner acknowledges receipt of request for continued examination under 37 CFR 1.114 and supplemental prior art filed 06/02/03.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicants' submission filed on 06/02/03 has been entered.

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84. Copy of Notice of Draftsperson's Patent Drawing Review, Form PTO-948 was attached to the office action of 04/08/03. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-7, 9-17 and 23 rejected under 35 U.S.C. 102(b) as being anticipated by Tormala et al. (US 5,084,051).

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Tormala discloses a biocomposite material that comprises at least partially porous bioceramic component and porous material component where the material component comprises resorbable polymer selected from the group consisting of polymer, copolymer, polymer mixture and ceramic materials and mixtures thereof (abstract, column 5, lines 9-64, column 6, lines 12-40 and claims 1 and 2). Specific polymers are polyglycolic acid, polylactic acid and others lists in Table 1 and claim 2 and these polymers are biodegradable. The bioceramic component and the polymer material component are mechanically reinforced with fibers (column 9, lines 1-10). The bioceramic component is composed of materials selected from calcium phosphate, fluoroapatite, calcium carbonate, magnesium calcium phosphate, bioglasses, glass ceramics or mixtures of ceramics (column 6, lines 41-46 and claim 4). In column 11, lines 2-14, Tormala discloses that the material component penetrates at least somewhat into the pores of the bioceramic during the manufacturing process of the biocomposite. The polymer component can be reinforced with fabric or with parallel or randomly oriented fibers and the reinforcement material can be made of resorbable materials such as polymer, copolymer, polymer mixture and/or ceramic material (column 8, lines 57-67 and column 9, lines 45-52). The teaching of Tormala meets the limitations of the claims.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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5. Claims 8 and 18-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tormala et al. (US 5,084,051).

Tormala discloses the biocomposite material of the instant claims but fails to disclose the amounts of the different polymers in the polymer mixture of the material component of the composite. Regarding claim 8, reinforcement structure could be any polymer disclosed in Tormala. In this regard, it may be noted that Tormala in column 9, lines 45-50 discusses that the reinforcement material can be any of the polymer disclosed in Tables 1 and 2 and also in example 4, PGA/PLLA fiber fabric is the reinforcement material. Thus the PGA/PLLA can be substituted for by any of the other polymers including poly-dioxanone (PDS) with the expectation of achieving the desired reinforcement.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare and use the biocomposite material of Tormala for bone surgical applications and wherein the material component of the biocomposite material comprises mixtures of polymer. One having ordinary skill in the art would have been motivated to use appropriate amounts of each of the polymer in the mixed polymer component with the expectation of providing desired mechanical properties.

6. Claim 24 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Tormala does not teach lyophilizing as a drying step.

7. Claims 25-28 are allowable because Tormala does not teach the method of claim 25.

8. Observation/Suggestion: The term PDS is recited in claim 8 without an initial definition of the term and an initial definition is requested with a parenthetical PDS for subsequent use.

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9. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Blessing Fubara
Patent Examiner
Tech. Center 1600
August 9, 2003

A handwritten signature in black ink, appearing to read "mfubara", is written over the printed name "Blessing Fubara".